IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.	:	10/056,418	Confirmation No.:	8065
Appellant	:	CAMPBELL, Todd		
Filed	:	January 22, 2002		
TC/A.U.	:	3734		
Examiner	:	NGUYEN, Vi X.		
Docket No.	:	P895		
Customer No.	:	28390		
Title	:	STENT ASSEMBLY WITH THERAPEUTIC AGENT EXTERIOR BANDING		

APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Dear Sir:

Please consider Appellant's brief as follows:

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1. REAL PARTY IN INTEREST

The real party in interest is Assignee Medtronic Vascular, Inc., a corporation having an office and a place of business at 3576 Unocal Place, Santa Rosa, California 95403.

2. RELATED APPEALS AND INTERFERENCES

Appellant and the undersigned attorneys are not aware of any appeals, judicial proceedings, or any interferences which may be related to, directly affect or be directly affected by, or have a bearing on the Board's decision in the pending appeal.

3. STATUS OF CLAIMS

Claims 34-36, 38, and 42 are pending. Claims 1-9, 37, and 39-41 were cancelled and claims 10-33 were withdrawn.

Claims 34-36, 38, and 42 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 20010020181 to Layne (the *Layne* application) in view of U.S. Patent No. 6,096,070 to Ragheb, *et al.* (the *Ragheb* patent).

Claims 34-36, 38, and 42 are the claims on appeal. *See* Claims Appendix.

4. STATUS OF AMENDMENTS

No amendments to the claims were filed subsequent to the final rejection mailed on January 25, 2007.

5. SUMMARY OF CLAIMED SUBJECT MATTER

In this Summary of Claimed Subject Matter, all citations are to the specification of United States Patent Application 10/056,418. All citations are illustrative only and additional support for the cited element may be found elsewhere in the specification. *See generally* FIGS 1-3; paragraphs [0029]-[0039].

Independent Claim 34:

A stent assembly **10** for implantation in a body lumen comprising: a stent **12**; and a plurality of bands **14** circumferentially wrapped around the stent **12**, the plurality of bands **14** including at least a first band and a second band, the width of each of the bands **14** being substantially less than the diameter of the stent **12**. *See* FIGS. 1 & 2; paragraph [0030]. The bands **14** further comprise a polymer containing a therapeutic agent, the bands **14** elastically gripping the stent **12**. *See* FIGS. 1 & 2; paragraph [0034]. Individual bands of the plurality of bands **14** contain different therapeutic agents, the first band containing a first therapeutic agent and the second band containing a second therapeutic agent, the first therapeutic agent being different than the second therapeutic agent. *See* Abstract; paragraphs [0029], [0030].

Independent Claim 35:

A stent assembly **10** for implantation in a body lumen comprising: a stent **12**; and a plurality of bands **14** circumferentially wrapped around the stent **12**, the plurality of bands **14** including at least a first band and a second band, the width of each of the bands **14** being substantially less than the diameter of the stent **12**. *See* FIGS. 1 & 2; paragraph [0030]. The bands **14** further comprise a polymer containing a therapeutic agent, the bands **14** elastically gripping the stent **12**. *See* FIGS. 1 & 2; paragraph [0034]. Individual bands **14** of the plurality of bands **14** are made of different polymers, the first bands **14** being made of a first polymer and the second band being made of a second polymer, the first polymer being different than the second polymer. *See* paragraphs [0034], [0035].

Independent Claim 36:

A stent assembly **10** for implantation in a body lumen comprising: a stent **12**; and at least one band **20** circumferentially wrapped around the stent **12**, the width of the band **20** being substantially less than the diameter of the stent **12**. *See* FIGS. 1-3; paragraphs [0030], [0038]. The band **20** further comprises a polymer containing a therapeutic agent, the band **20** elastically gripping the stent **12**, the polymer comprising a first polymer and a second polymer, the first polymer being different than the second polymer. *See* paragraph [0038]. The band **20** further comprises a first layer **22** and a second layer **24**, the first layer **22** located circumferentially around the stent **12**, and the second layer **24** attached circumferentially around the first layer **22**, the first layer **22** being made of the first polymer and the second layer **24** being made of the second polymer. *See* FIG. 3; paragraph [0038].

Independent Claim 42:

A stent assembly **10** for implantation in a body lumen comprising: a stent **12**; and at least one band **20** circumferentially wrapped around the stent **12**, the width of the band **20** being substantially less than the diameter of the stent **12**. *See* FIGS. 1-3; paragraphs [0030], [0038]. The band **20** further comprises a polymer containing a therapeutic agent, the band **20** elastically gripping the stent **12**, the therapeutic agent comprising a first therapeutic agent and a second therapeutic agent, the first therapeutic agent being different than the second therapeutic agent. *See* paragraph [0038]. The band **20** further comprises a first layer **22** and a second layer **24**, the first layer **22** located circumferentially around the stent **12**, and the second layer **24** attached circumferentially around the first layer **22**, the first layer **22** containing the first therapeutic agent and the second layer **24** containing the second therapeutic agent. *See* FIG. 3; paragraph [0038].

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 34-36, 38, and 42 are unpatentable under 35 U.S.C. §103(a) over U.S. Patent Publication No. 20010020181 to Layne (the *Layne* application) in view of U.S. Patent No. 6,096,070 to Ragheb, *et al.* (the *Ragheb* patent).

7. ARGUMENTS

The Appellant respectfully submits that claims 34-36, 38, and 42 are allowable over U.S. Patent Publication No. 20010020181 to Layne (the *Layne* application) in view of U.S. Patent No. 6,096,070 to Ragheb, *et al.* (the *Ragheb* patent), and that the rejection of claims 34-36, 38, and 42 should be reversed.

35 U.S.C. §103 Rejections

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all the claim limitations. *See* MPEP 2143. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). *See* MPEP 2143.03. The Appellant respectfully asserts that the cited references fail to meet any of the three basic criteria.

The *Layne* application discloses that a series of spaced apart ePTFE circumferential bands can be placed over the top of longitudinal strips and ringed stents. All of the components of the structure are then laminated to the inner ePTFE tube to capture the stent. By selecting the size and position of the ePTFE bands, it is possible to leave critical parts of the stent unencapsulated to facilitate flexibility and expansion. *See* Abstract. The ePTFE tube connected to the stent prevents cellular infiltration through the stent and restenosis. *See* paragraphs [0005]-[0007]. The circumferential ePTFE bands **52** hold ring stents **30** in place. The spaces between the bands of ePTFE **52** can be altered to control the degree of flexibility and stability desired. After the strips **50** and/or bands **52** are configured in the desired pattern onto each of the structures **10** and **60**, the structures are exposed to heat and pressure, such as that caused by wrapping with PTFE tape, thereby causing the ePTFE regions of the strips **50** and/or bands **52** to fuse or laminate to the tubular graft **20**. *See* FIG. 3; paragraphs [0020], [0021]. The ePTFE bands do not elastically grip the ring stents,

but are fused to the tubular graft with the ring stents trapped in between. The *Layne* application does not disclose use of a drug or therapeutic agent with the ePTFE circumferential bands, inner ePTFE tube, stent, or any other component. In fact, the *Layne* application does not include the words "drug," "therapeutic agent," or any like word.

The *Ragheb* patent discloses a coated implantable medical device **10** such as a coronary stent with at least one layer **18** of a bioactive material posited on one surface, and at least one porous layer **20** posited over the bioactive material layer **18**. The porous layer **20** comprises a polymer applied preferably by vapor or plasma deposition and provides a controlled release of the bioactive material. *See* FIG. 1; Abstract. Degradation of an agent, a drug or a bioactive material applied to a vascular stent or other implantable medical device may be avoided by covering the agent, drug or bioactive material with a porous layer of a biocompatible polymer that is applied without the use of solvents, catalysts, heat or other chemicals or techniques, which would otherwise be likely to degrade or damage the agent, drug or material. *See* column 3, lines 7-20.

A. The cited references when combined fail to teach or suggest all the claim limitations, as required to establish a prima facie case of obviousness under 35 U.S.C. §103.

The Appellant respectfully asserts that the *Layne* application and the *Ragheb* patent, alone or in combination, fail to teach or suggest all the claim limitations. The cited references fail to disclose, teach, or suggest a stent assembly having a band circumferentially wrapped about a stent, comprising a polymer containing a therapeutic agent, and elastically gripping the stent, as recited in independent claims 34, 35, 36, and 42.

The cited references fail to disclose a band comprising a polymer containing a therapeutic agent as claimed. The *Layne* application discloses a series of spaced apart ePTFE circumferential bands. *See* Abstract. As noted by the Examiner, the *Layne* application is silent regarding the bands containing different therapeutic agents, but

the *Layne* application is also silent as to the bands containing any therapeutic agent. The terms "drug" or "therapeutic agent" do not appear in the *Layne* application, which operates on the principle that the ePTFE tube prevents cellular infiltration through the stent and restenosis. *See* paragraph [0007]. Therefore, no drug is necessary in the *Layne* application. The *Ragheb* patent discloses a coated implantable medical device, but the coating is applied to the surface of the stent and not to a band. *See* Abstract. The *Ragheb* patent fails to disclose a band or any other component wrapped around the stent. The *Ragheb* patent relies on a layer of bioactive material posited over the surface of a structure for drug delivery, so no band is necessary.

The cited references also fail to disclose a band elastically gripping the stent. The *Layne* application discloses a series of spaced apart ePTFE circumferential bands. *See* Abstract. The strips and/or bands are configured in the desired pattern onto each of the structures, the structures are exposed to heat and pressure, thereby causing the ePTFE regions of the strips and/or bands to fuse or laminate to the tubular graft. *See* paragraph [0021]. Therefore, the *Layne* application depends on fusing the ePTFE circumferential bands to the tubular graft to retain the ePTFE circumferential bands on the stent, rather than the bands elastically gripping the stent. In fact, the ePTFE material, which is the only band material disclosed in the *Layne* application, is inelastic and so incapable of gripping the stent. PTFE is stretched to several hundred percent of its original length to form ePTFE. *See* paragraph [0006]. Radial expansion of a stent may stress and tear an ePTFE cover. *See* paragraph [0007]. Therefore, the band of the *Layne* application is not elastic and cannot elastically grip the stent. The *Ragheb* patent fails to disclose a band at all, let alone a band capable of elastically gripping the stent.

Claim 38 depends directly from independent claim 34 and so includes all the elements and limitations of its independent claim. The Appellant therefore respectfully submits that the dependent claim is allowable over the *Layne* application and the *Ragheb* patent for at least the same reasons as set forth above with respect to its independent claim.

B. There is no suggestion or motivation to combine the reference teachings, as required establish a prima facie case of obviousness under 35 U.S.C. §103.

The Appellant respectfully asserts that there is no suggestion or motivation to combine the reference teachings. The *Layne* application is directed to the problem of providing an ePTFE tube on a stent and the *Ragheb* patent is directed to the problem of avoiding drug degradation in the coating process. In addition, the *Layne* application has a completely different principle of operation than the *Ragheb* patent. The *Layne* application uses the ePTFE tube without any drug to prevent restenosis, while the *Ragheb* patent relies on bioactive materials. *See* the *Layne* application at paragraph [0007] *versus* the *Ragheb* patent at column 5, lines 48-51. The former operates without the use of drugs while the latter requires them. Therefore, there is no motivation to combine the *Layne* application and the *Ragheb* patent.

C. There is no reasonable expectation of success from combining the cited references, as required to establish a prima facie case of obviousness under 35 U.S.C. §103.

The Appellant respectfully asserts that there is no reasonable expectation of success from combining the cited references. The *Layne* application discloses a drug-free system for structurally supporting an ePTFE tube on a stent and the *Ragheb* patent discloses applying a porous coating over a biological material on a stent. One of ordinary skill in the art would not expect success in combining the inventions of the *Layne* application and the *Ragheb* patent to produce a stent assembly having a band circumferentially wrapped about a stent, comprising a polymer containing a therapeutic agent, and elastically gripping the stent, as claimed by the Appellant.

Further, both the *Layne* application and the *Ragheb* patent teach away from the Appellant's invention. The *Layne* application teaches that using an ePTFE tube can prevent restenosis, and so teaches away from using any therapeutic agent, i.e., no therapeutic agent as claimed by the Appellant is required. *See* paragraphs [0007], [0016]. The *Ragheb* patent teaches a biological material restrained by a porous polymer coating, and so teaches away from using a band to deliver the biological

material, i.e., no band comprising a polymer containing a therapeutic agent as claimed by the Appellant is required.

The preferred embodiment of the *Ragheb* patent also teaches that the biological material is disposed on the stent without a polymer mixed with the biological material, and so teaches away from bands further comprising a polymer containing a therapeutic agent as claimed. The *Ragheb* patent teaches that it can be particularly convenient to apply a mixture of the bioactive material or materials and a volatile fluid over the structure, and then remove the fluid in any suitable way, for example, by allowing it to evaporate. *See* column 17, lines 47-50. Without regard to the method of application, however, what is important is that the bioactive material need only be physically held in place until the porous layer **20** is deposited over it. This can avoid the use of carriers, surfactants, chemical binding and other such methods often employed to hold a bioactive agent on other devices. The additives used in such methods may be toxic, or the additives or methods may alter or degrade the bioactive agent, rendering it less effective, or even toxic itself. *See* column 17, lines 56-65. Any mixing of a bioactive material from the layers **18** and/or **22** into the porous layers **20** and/or **24**, prior to introducing the device 10 into the vascular system of the patient, is unintentional and merely incidental. *See* FIG. 2; column 13, lines 57-61.

Reversal of the rejection of claims 34-36, 38, and 42 under 35 U.S.C. §103(a) as being unpatentable over the *Layne* application in view of the *Ragheb* patent is respectfully requested.

8. SUMMARY

The Appellant respectfully submits that claims 34-36, 38, and 42 fully satisfy the requirements of 35 U.S.C. §§102, 103 and 112. In view of the foregoing, reversal of the rejection of claims 34-36, 38, and 42 under 35 U.S.C. §103(a) is respectfully requested.

Respectfully submitted,

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9. CLAIMS APPENDIX

Claims 1-9 (canceled)

Claim 10 (withdrawn): The stent assembly of claim 9 wherein at least one of the layers is biodegradable.

Claim 11 (withdrawn): The stent assembly of claim 9 wherein the first layer contains one therapeutic agent and the second layer contains a different therapeutic agent.

Claim 12 (withdrawn): The stent assembly of claim 1 wherein the band further comprises a plurality of interwoven filaments.

Claim 13 (withdrawn): The stent assembly of claim 12 wherein individual filaments of the plurality of interwoven filaments contain different therapeutic agents.

Claim 14 (withdrawn): The stent assembly of claim 12 wherein individual filaments of the plurality of interwoven filaments are made of different polymers.

Claim 15 (withdrawn): A stent assembly for implantation in a body lumen comprising:

a stent; and

at least one helical wrap helically wrapped around the stent, the width of the helical wrap being substantially less than the diameter of the stent;

wherein the helical wrap further comprises a polymer containing a therapeutic agent.

Claim 16 (withdrawn): The stent assembly of claim 15 wherein the therapeutic agent is selected from the group consisting of pharmaceutical agents, radioactive agents, bioactive agents, and combinations thereof.

Claim 17 (withdrawn): The stent assembly of claim 15 wherein the therapeutic agent is selected from the group consisting of thrombin inhibitors, antithrombogenic agents, thrombolytic agents, fibrinolytic agents, vasospasm inhibitors, calcium channel blockers, vasodilators, antihypertensive agents, antimicrobial agents, antibiotics, inhibitors of surface glycoprotein receptors, antiplatelet agents, antimitotics, microtubule inhibitors, anti secretory agents, actin inhibitors, remodeling inhibitors, antisense nucleotides, anti metabolites, antiproliferatives, anticancer chemotherapeutic agents, anti-inflammatory steroid or non-steroidal anti-inflammatory agents, immunosuppressive agents, growth hormone antagonists, growth factors, dopamine agonists, radiotherapeutic agents, peptides, proteins, enzymes, extracellular matrix components, inhibitors, free radical scavengers, chelators, antioxidants, anti polymerases, antiviral agents, photodynamic therapy agents, gene therapy agents, and combinations thereof.

Claim 18 (withdrawn): The stent assembly of claim 15 wherein the polymer is selected from the group consisting of a single polymer, a copolymer blend, a polymer mixture, a copolymer mixture, and a polymer-copolymer mixture.

Claim 19 (withdrawn): The stent assembly of claim 15 wherein the polymer is selected from the group consisting of a biostable polymer, a bioabsorbable polymer, and a biomolecular polymer.

Claim 20 (withdrawn): The stent assembly of claim 15 wherein the polymer is selected from the group consisting of poly(L-lactic acid), polycaprolactone, poly(lactide-co-glycolide), poly(hydroxybutyrate), poly(hydroxybutyrate-co-valerate), polydioxanone, polyorthoester, polyanhydride, poly(glycolic acid), poly(D,L-lactic acid), poly(glycolic acid-co-trimethylene

carbonate), polyphosphoester, polyphosphoester urethane, poly(amino acids), cyanoacrylates, poly(trimethylene carbonate), poly(iminocarbonate), copoly(ether-esters), PEO/PLA, polyalkylene oxalates, polyphosphazenes, fibrin, fibrinogen, cellulose, starch, collagen and hyaluronic acid, polyurethanes, silicones, polyesters, polyolefins, polyisobutylene, ethylene-alphaolefin copolymers, acrylic polymers, acrylic copolymers, vinyl halide polymers, vinyl halide copolymers, polyvinyl chloride, polyvinyl ethers, polyvinyl methyl ether, polyvinylidene halides, polyvinylidene fluoride, polyvinylidene chloride, polyacrylonitrile, polyvinyl ketones, polyvinyl aromatics, polystyrene, polyvinyl esters, polyvinyl acetate, copolymers of vinyl monomers, copolymers of vinyl monomers with olefins, ethylene-methyl methacrylate copolymers, acrylonitrile-styrene copolymers, ABS resins, ethylene-vinyl acetate copolymers, polyamides, nylon 66, polycaprolactam, alkyd resins, polycarbonates, polyoxymethylenes, polyimides, polyethers, epoxy resins, polyurethanes, rayon, rayon-triacetate, cellulose, cellulose acetate, cellulose butyrate, cellulose acetate butyrate, cellophane, cellulose nitrate, cellulose propionate, cellulose ethers, carboxymethyl cellulose, and mixtures thereof.

Claim 21 (withdrawn): The stent assembly of claim 15 further comprising a plurality of helical wraps.

Claim 22 (withdrawn): The stent assembly of claim 15 wherein the helical wrap further comprises a first layer and a second layer, the first layer located around the stent, and the second layer attached around the first layer.

Claim 23 (withdrawn): The stent assembly of claim 22 wherein at least one of the layers is biodegradable.

Claim 24 (withdrawn): The stent assembly of claim 22 wherein the first layer contains one therapeutic agent and the second layer contains a different therapeutic agent.

Claim 25 (withdrawn): The stent assembly of claim 15 wherein the helical wrap further comprises a plurality of interwoven filaments.

Claim 26 (withdrawn): The stent assembly of claim 25 wherein individual filaments of the plurality of interwoven filaments contain different therapeutic agents.

Claim 27 (withdrawn): The stent assembly of claim 25 wherein individual filaments of the plurality of interwoven filaments are made of different polymers.

Claim 28 (withdrawn): A stent assembly for implantation in a body lumen comprising:

means for supporting walls of the body lumen; and

means for eluting a therapeutic agent, the eluting means removably wrapped around the supporting means, the width of the eluting means being substantially less than the diameter of the supporting means.

Claim 29 (withdrawn): The stent assembly of claim 28 wherein the eluting means is at least one band circumferentially wrapped around the supporting means.

Claim 30 (withdrawn): The stent assembly of claim 28 wherein the eluting means is a helical wrap helically wrapped around the supporting means.

Claim 31 (withdrawn): The stent assembly of claim 28 wherein the therapeutic agent is selected from the group consisting of pharmaceutical agents, radioactive agents, bioactive agents, and combinations thereof.

Claim 32 (withdrawn): The stent assembly of claim 28 wherein the eluting means comprises a polymer selected from the group consisting of a single

polymer, a copolymer blend, a polymer mixture, a copolymer mixture, and a polymer-copolymer mixture.

Claim 33 (withdrawn): The stent assembly of claim 28 wherein the eluting means comprises a polymer selected from the group consisting of a biostable polymer, a bioabsorbable polymer, and a biomolecular polymer.

Claim 34 (on appeal): A stent assembly for implantation in a body lumen comprising:

a stent; and

a plurality of bands circumferentially wrapped around the stent, the plurality of bands including at least a first band and a second band, the width of each of the bands being substantially less than the diameter of the stent;

wherein the bands further comprise a polymer containing a therapeutic agent, the bands elastically gripping the stent; and

wherein individual bands of the plurality of bands contain different therapeutic agents, the first band containing a first therapeutic agent and the second band containing a second therapeutic agent, the first therapeutic agent being different than the second therapeutic agent.

Claim 35 (on appeal): A stent assembly for implantation in a body lumen comprising:

a stent; and

a plurality of bands circumferentially wrapped around the stent, the plurality of bands including at least a first band and a second band, the width of each of the bands being substantially less than the diameter of the stent;

wherein the bands further comprise a polymer containing a therapeutic agent, the bands elastically gripping the stent; and

wherein individual bands of the plurality of bands are made of different polymers, the first band being made of a first polymer and the second band

being made of a second polymer, the first polymer being different than the second polymer.

Claim 36 (on appeal): A stent assembly for implantation in a body lumen comprising:

a stent; and

at least one band circumferentially wrapped around the stent, the width of the band being substantially less than the diameter of the stent;

wherein the band further comprises a polymer containing a therapeutic agent, the band elastically gripping the stent, the polymer comprising a first polymer and a second polymer, the first polymer being different than the second polymer; and

wherein the band further comprises a first layer and a second layer, the first layer located circumferentially around the stent, and the second layer attached circumferentially around the first layer, the first layer being made of the first polymer and the second layer being made of the second polymer.

Claim 37 (cancelled):

Claim 38 (on appeal): The stent assembly of claim 34 wherein the stent has a proximal portion and a distal portion, the first band being disposed on the proximal portion and the second band being disposed on the distal portion.

Claim 39-41 (cancelled):

Claim 42 (on appeal): A stent assembly for implantation in a body lumen comprising:

a stent; and

at least one band circumferentially wrapped around the stent, the width of the band being substantially less than the diameter of the stent;

wherein the band further comprises a polymer containing a therapeutic agent, the band elastically gripping the stent, the therapeutic agent comprising a first

therapeutic agent and a second therapeutic agent, the first therapeutic agent being different than the second therapeutic agent; and

wherein the band further comprises a first layer and a second layer, the first layer located circumferentially around the stent, and the second layer attached circumferentially around the first layer, the first layer containing the first therapeutic agent and the second layer containing the second therapeutic agent.

10. EVIDENCE APPENDIX

None.

11. RELATED PROCEEDINGS APPENDIX

None.